

Message

From: Keigwin, Richard [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=151BAABB6A2246A3A312F12A706C0A05-RICHARD P KEIGWIN JR]
Sent: 6/27/2017 10:50:32 AM
To: Steve Knizner (Knizner.Steve@epa.gov) [Knizner.Steve@epa.gov]; Weiss, Steven [Weiss.Steven@epa.gov]
CC: Arnold Layne (Layne.Arnold@epa.gov) [Layne.Arnold@epa.gov]
Subject: FW: Thank you and follow ups -- ACC
Attachments: Regulation by Guidance or Unwritten Policies.docx; Undocumented Expansion of Data Requirements.docx

We should develop a response. Thanks.

From: Jain, Komal [mailto:Komal_Jain@americanchemistry.com]
Sent: Friday, June 23, 2017 3:51 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Subject: RE: Thank you and follow ups

Dear Rick,

Attached please find two papers that provide the additional information on two critical issues we raised during our meetings on May 10 and May 24. Again, we truly appreciate these open lines of communication and hope that you will find these helpful.

Please do not hesitate to contact me if you have any questions. We look forward to your feedback.

With warm regards,
Komal

Komal K. Jain, J.D. | American Chemistry Council
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From: Jain, Komal
Sent: Friday, May 26, 2017 1:59 PM
To: 'keigwin.richard@epa.gov' <keigwin.richard@epa.gov>
Subject: Thank you and follow ups
Importance: High

Dear Rick:

I want to thank you for meeting with us on Wednesday to follow up on issues raised with Administrator Pruitt on May 10. While we discussed our most pressing and recent issues, it is clear that it would be most helpful for you if we provided more examples to underscore some of the concerns we raised with Administrator Pruitt. Thus, by no later than June 23, I intend to provide you two papers to provide additional information.

The first will address our concerns about "regulation by guidance". We will provide several examples of when a shift in a significant EPA policy or practice for antimicrobials was discussed only within an EPA document with no clear associated

notice or comment period. As we discussed, the Panel is not advocating rulemaking for all EPA actions, but rather, asking that EPA recognize the impact of certain guidance by making the entire registrant community aware of it in advance of implementation and providing the reasons for the guidance through a notice in the *Federal Register*, via the *OPP website* or other public mechanism, with an associated opportunity for comment.

The second will address our concern that at times EPA asks for data from registrants through the re-registration or registration process that it has not asked for before. We describe this as “EPA’s curiosities” since the basis for the request for “new” data is not made apparent to the recipient. We also will try to quantify how these additional data burdens impact business; thereby diverting resources from innovation.

ACC and the Biocides Panel appreciate the opportunity to discuss these concerns with you. Our objective is to improve the registration process so that it is more efficient and transparent for both industry and EPA. We welcome the willingness of the Agency for additional dialogue in order to achieve our shared goals.

Best,
Komal

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